GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:3682
ANSWERED ON:24.03.2017
Joint Inspection of Pharma Manufacturing Units
Gopal Dr. K.

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the European Union (EU) has agreed for joint inspection of pharma manufacturing units in India;

(b) if so, the details thereof;

(c) whether it is true that the EU has banned several drugs and, if so, the details thereof;

(d) whether India has stressed on interactions to address cultural differences and misunderstandings; and

(e) if so, the response of the EU in this regard?

Answer

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)
(a): No such agreement has been signed between European Union and Central Drugs Standard Control Organization.
(b): Does not arise.
(c): EU has asked several exporters across the globe, including India, to withdraw certain drugs that are manufactured and exported based on clinical trials conducted by GVK Biosciences, India due to data integrity issues in the clinical trials conducted by the said company.
(d) & (e): The related issues have been discussed between Indian and European authorities in a series of meetings.
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